

K892360 WATER JEL STERILE GEL-SOAKED BURN DRESSINGJun 5, 1989
60 days to decisionK892360 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k892360/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Apr 6, 1989
Decision date	Jun 5, 1989
Days to decision	60 days
Third-party review	No

APPLICANT

Company	Pfizer, Inc.
Location	Mchenry, IL, US
Contact	DAVID OPPENHEIMER
510(k) history	30 submissions · 30 cleared · 1977-2018

Pfizer, Inc. is an American multinational pharmaceutical and biotechnology corporation headquartered in Manhattan, New York City. Founded in 1849, Pfizer is one of the oldest pharmaceutical companies in North America. Pfizer's FDA 510(k) regulatory record includes cleared devices from total submissions, spanning 1977 to 2018. The company's device portfolio demonstrates strength in orthopedic devices, including surgical implants and fixation systems. This regulatory activity is now historical, with no clearances recorded in the past five years. The company's cleared device...
